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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/926,534	01/22/2002	Abderrahim Bennis	01198	7735

23338 7590 08/13/2003

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EXAMINER

OSTRUP, CLINTON T

ART UNIT	PAPER NUMBER
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1614

DATE MAILED: 08/13/2003

7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application N .

09/926,534

Applicant(s)

BENNIS ET AL.

Examiner

Clinton Ostrup

Art Unit

1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5/26/03.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☒ Claim(s) 22 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Claims 1-28 are pending in this application.

Response to Applicant's Arguments/Amendment

Withdrawn Claim Rejections - 35 USC § 102

Applicant's arguments and amendment filed May 26, 2003, Paper No. 8, to the rejection of claims 1-3, 4-5, and 10 under 35 U.S.C. 102(b) as being anticipated by Helden et al., 3,607,271 have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's arguments and amendment filed May 26, 2003, Paper No. 8, to the rejection of claims 1-3 under 35 U.S.C. 102(b) as being anticipated by Kotz & Treichel, Chemistry & Chemical Reactivity, Third Edition, pp.860-861, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Applicant's arguments and amendment filed May 26, 2003, Paper No. 8, to the rejection of claims 1-9 under 35 U.S.C. 102(b) as being anticipated by Bayer Bitterfeld GmbH, Almany, Alka-Seltzer, have been fully considered and deemed persuasive. Therefore, the said rejection has been withdrawn.

Maintained Claim Rejections - 35 USC § 103

Applicant's arguments and amendment filed May 26, 2003, Paper No. 8, to the rejection of claims 1-10 under 35 U.S.C. 103(a) as being unpatentable over Lafon, UK 904,955 taken with Blonde, UK 1,227,744 and further in view of Bayer Bitterfeld GmbH, Almany, Alka-Seltzer, have been fully considered. However, they have not been found

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convincing and therefore, the said rejection has been MAINTAINED and applied to newly submitted claims 11-28.

Applicant argues that the Tyrode solution of Lafon is only used in connection with *in vitro* administration of phloroglucinol and that the diluents and carriers do not appear to be buffers. The examiner respectfully agrees that the Tyrode solution of Lafon is only explicitly taught as being administered *in vitro*. However, this rejection is based on a combination of references and applicant's arguments against the references individually cannot show nonobviousness where the rejections are based on the combination of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

In regard to applicant's argument that the diluents and carriers suggested by Lafon are somehow limited to glucose, lactose, starch, magnesium stearate, sodium lauryl sulfate, talc, gelatin and wax, the examiner respectfully disagrees. The test for obviousness is what the combined teachings of the references would have suggested to those of ordinary skill in the art and one skilled in the art. Lafon teaches a composition comprising phloroglucinol in a unit dosage form for oral administration, Blonde teaches that patients prefer in solution more than as tablets or capsules and that lumps of the composition containing the medicaments instantaneously dissolve in water and are intended for oral administration and Alka-Seltzer teaches an effervescent tablet comprising citric acid, sodium bicarbonate, acetylsalicylate acid with saccharine sodium, and sodium benzoate.

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Applicant further argues that there is no specific reason to have modified the phloroglucinol containing compositions of Lafon and Blonde by adding phloroglucinol to the effervescent tablet taught by Alka-Seltzer, other than those suggested by the instant invention (e.g. the appreciable greater antispasmodic activity of the buffered, effervescent tablet).

The examiner respectfully disagrees. Phloroglucinol is a well-known antispasmodic. Alka-Seltzer teaches a composition comprising citric acid, sodium bicarbonate and is in the form of an effervescent tablet. Alka-Seltzer keeps gastric pH between 5-7 and has been used to treat upset stomachs, including spasms for many years.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the phloroglucinol containing compositions of the primary and secondary references, by adding phloroglucinol to the effervescent tablet as taught by Alka-Seltzer, because of the reasonable expectation of obtaining an effervescent tablet capable of delivering an oral dosage form of the antispasmodic active ingredient in a tablet form which is quickly dissolvable in water.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lafon, UK 904,955 taken with Blonde, UK 1,227,744 and further in view of Bayer Bitterfeld GmbH, Almany, Alka-Seltzer.

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Lafon teaches pharmaceutical compositions containing phloroglucinol, wherein said compositions are made in a Tyrode solution. A Tyrode solution contains sodium chloride, potassium chloride, crystalline calcium chloride, hydrated magnesium chloride, sodium bicarbonate, sodium phosphate, glucose and water. The primary reference teaches phloroglucinol in the form of cachets, capsules, powders, and tablets, which all give equally good results when administered orally. The reference teaches that other substances may be administered with the phloroglucinol such as solid or liquid carriers or a dispersants and specifically teach examples of cachets, capsules, sugared tablets, and injectable ampoules in Examples 1-6 on page 3.

Blonde teaches compositions comprising phloroglucinol, sodium saccharinate, and other substances such as acetyl-salicylic acid. The secondary reference teaches that the compositions can be in the form of lumps containing medicaments and said lumps are used because they allow the drugs to be instantly dissolved in water, allowing the drugs to be delivered orally in solutions.

Although the primary and secondary references both teaches solid and liquid forms of compositions comprising phloroglucinol for oral administration, the references are silent with respect to the pH of the compositions and lack the acids of instant claim 4-5 and 9 as well as the effervescent tablet of instant claims 7-9.

Alka-Seltzer comprises citric acid, sodium bicarbonate and is in the form of an effervescent tablet.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the phloroglucinol containing compositions of the

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primary and secondary references, by adding phloroglucinol to the effervescent tablet as taught by Alka-Seltzer, because of the reasonable expectation of obtaining an effervescent tablet capable of delivering an oral dosage form of the antispasmodic active ingredient in a tablet form which is quickly dissolvable in water.

New Claim Objections

Claim 22 is objected to because of the following informalities: It appears applicant misspelled "maintaining" as "maintain". Appropriate correction is required.

New Claim Rejections

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 22-28 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 22 recites the limitation "the medium," however, there is insufficient antecedent basis for this limitation in the claim.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (703) 308-3627. The examiner can normally be reached on 8:00am - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel can be reached on (703) 308-4725. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

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Clinton Ostrup
Examiner
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A handwritten signature in black ink, appearing to read 'Clinton Ostrup', written in a cursive style.

Frederick Krass
Primary Examiner
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A handwritten signature in black ink, appearing to read 'Frederick Krass', written in a cursive style.

August 11, 2003